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Notice of References Cited	Application/Control No. 09/922,327	Applicant(s)/Patent Under Reexamination KOTIN ET AL.	
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(12) **United States Patent**
Wiener et al.

(10) **Patent No.: US 6,342,390 B1**
(45) **Date of Patent: *Jan. 29, 2002**

(54) **LIPID VESICLES CONTAINING ADENO-ASSOCIATED VIRUS REP PROTEIN FOR TRANSGENE INTEGRATION AND GENE THERAPY**

(75) Inventors: **Stephen M. Wiener**, Bethesda; **John A. Chiorini**; **Brian Safer**, both of Silver Spring; **Robert M. Kotin**, Rockville, all of MD (US); **Matthew D. Weitzman**, La Jolla, CA (US); **Roland A. Owens**, Arlington, VA (US)

(73) Assignee: **The United States of America as represented by the Secretary of Health and Human Services**, Washington, DC (US)

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This patent is subject to a terminal disclaimer.

(21) Appl. No.: **08/344,729**

(22) Filed: **Nov. 23, 1994**

(51) **Int. Cl.**[7] **C12N 15/00**

(52) **U.S. Cl.** **435/325**; 435/320.1; 435/372.3; 435/455; 435/458; 514/2; 514/44; 424/93.1; 424/93.21; 530/350

(58) **Field of Search** 435/320.1, 172.3, 435/240.1, 240.2, 240.25, 455, 458, 325–372.3; 424/93.1, 93.21; 514/44, 2; 530/350

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(57) **ABSTRACT**

A composition for delivering at least one DNA sequence encoding a desired protein or polypeptide (such as a therapeutic agent) to a cell. The composition comprises an adeno-associated virus rep protein (or a nucleic acid sequence encoding an adeno-associated virus rep protein) and a genetic construct including at least one DNA sequence encoding a protein or polypeptide or genetic transcript of interest and a promoter controlling the at least one DNA sequence. The genetic construct also includes a first adeno-associated virus ITR or protein or derivative thereof and a second adeno-associated virus ITR or a portion or derivative thereof. The first and second adeno-associated virus ITRs or portions or derivatives thereof flank the at least one DNA sequence encoding the protein or polypeptide or genetic transcript of interest and the promoter controlling the at least one DNA sequence encoding the protein or polypeptide or genetic transcript of interest. Such a composition provides for integration of genetic material at a specific locus in the human chromosome, while minimizing the possibility of inadvertent inactivation of host genes and minimizing the possibility of viral contamination.

18 Claims, 13 Drawing Sheets